



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: FEI 3001465117

Public Health Service 53637d
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5703

03-BLT-04

October 22, 2002

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Leif Klasson
Owner
Swedish Fish Company
3461 Washington Boulevard
Arlington, VA 22201

Dear Mr. Klasson,

On September 18, 2002 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 3461 Washington Boulevard, Arlington, VA. The inspection was conducted to determine your firm's compliance with FDA's Fish and Fishery Products regulations at Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practices regulations for food at Title 21, Code of Federal Regulations, Part 110 (21 CFR 110).

During our inspection, the FDA investigators observed serious deviations from the regulations. The FDA investigators provided you with a copy of the investigators' observations (FDA Form 483) and the Import Seafood HACCP Report (form FDA 3502), which present the investigators' evaluation of the firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

1. Your firm does not have written HACCP plans to control any food safety hazards that are identified as reasonably likely to occur, as required by 21 CFR § 123.6(b). Specifically, your firm does not have written HACCP plans for all seafood products including, but not limited to swordfish, salmon, tuna, halibut, grouper, shellfish products, and crustaceans.
2. Failure to maintain sanitation control records that, at a minimum, document the monitoring and corrections of problems involving: (1) safety of water that comes into contact with food or food contact surfaces; (2) safety of water used to manufacture ice; (3) prevention of cross-contamination; (4) maintenance of hand washing, hand sanitizing, and toilet facilities; (5) protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; (6) proper labeling, storage, and use of toxic compounds; (7) control of employee health conditions that could result in microbiological contamination; (8) and exclusion of pests from the facility (21 CFR § 123.11(c)).
3. Fish or fishery products were obtained from a country (Norway) that lacks an active memorandum of understanding or similar agreement with FDA, and no adequate written

verification procedures were implemented to ensure that these fish and fishery products had been processed in accordance with 21 CFR § 123.12(a).

4. Failure to maintain equipment, containers, and utensils used to convey and store food in a manner that protects against contamination (21 CFR § 110.80(b)(7)). For example:
 - Knives and other utensils used in the processing of seafood products were observed being stored in a bucket of dirty water that contained no detectable level of sanitizer. Employees were observed using utensils from this bucket to process fish without first washing and sanitizing them.
 - Accumulated old fish product was observed in etched portions of the poly cutting boards used to cut fish in the processing area.
 - No sanitizer is currently being used to clean equipment and food contact surfaces.
 - Accumulated flaking rust was observed on the interior ceiling of the ice machine in the back room, used to store ice for packing fish.
 - Accumulated flaking rust and dust were observed on the fan guards of the cooling unit located above the equipment sink and above/beside the processing tables in the processing area.
5. Failure to take effective measures to protect finished food from contamination by raw materials in that, raw salmon was observed being stored directly on top of cooked crab meat in the walk-in cooler, directly adjacent to the processing area (21 CFR § 110.80(b)(6)).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. We note that FDA documented similar deviations during your last inspection on May 21, 2001. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/ or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

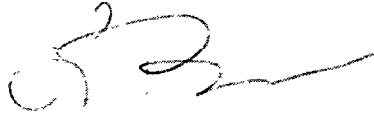
Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be made within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Edward M. Creech, Jr., Compliance Officer, 7737 Hampton Blvd., Warehouse 4C, Room 206, Norfolk, VA 23505.

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October 22, 2002

If you have questions regarding this letter or the implementation of the HACCP regulation, you may contact Mr. Creech at (757) 441-3787 extension 11.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lee Bowers', with a stylized flourish at the end.

Lee Bowers
Director, Baltimore District

cc: Mr. David Fry, General Manager
Mr. Stephen W. Soboloski, Buyer/ Sale Representative
Swedish Fish Company
3461 Washington Boulevard
Arlington, VA 22201